

EUA Amendment Review Memorandum Addendum

Date: September 28, 2022

To: The File

From: Peter Marks, MD, PhD (CBER/OD)

EUA Application Number: 27073

Product: Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (mRNA-1273.222)

Subject: Addendum #2 (DP batches 017H22A, 021H22A, 013H22A, 019H22A, 020H22A, 023H22A, 049D22A, 061F22A and 024H22A) to the September 20, 2022 memorandum entitled “Assessment of certain Moderna COVID-19 Vaccine, Bivalent Batches”

The purpose of this addendum is to document the Agency’s determination regarding the disposition of Moderna COVID-19 Vaccine, Bivalent DP batches 017H22A, 021H22A, 013H22A, 019H22A, 020H22A, 023H22A, 049D22A, 061F22A and 024H22A .

Disposition of Moderna COVID-19 Vaccine, Bivalent DP batches 017H22A, 021H22A, 013H22A, 019H22A, 020H22A, 023H22A, 049D22A, 061F22A and 024H22A

In light of concerns about potential supply limitations, Moderna requested that FDA review and authorize under the EUA certain batches of Moderna bivalent final DP produced at the Catalent facility. Although FDA does not intend to determine whether to add Catalent as an authorized manufacturing facility for the Moderna COVID-19 Vaccine, Bivalent until the Agency’s evaluation of the recent inspection is complete, in the interim, FDA can authorize batches of Moderna bivalent DP produced at this facility provided that FDA has sufficient data and information to conclude these batches are suitable for use.

Moderna submitted data and information supporting the quality of nine bivalent booster final DP batches—017H22A, 021H22A, 013H22A, 019H22A, 020H22A, 023H22A, 049D22A, 061F22A and 024H22A —manufactured at the Catalent facility. Specifically, Moderna provided the results of its comprehensive batch review, which included, for example, data and analysis covering, environmental monitoring, media fills, and particle characterization. OVRP has carefully reviewed this information and determined that all applicable specifications were met for these batches. Thus, OVRP does not have safety, effectiveness, or quality concerns with these batches, and has concluded that they are suitable for use.

Further, (b) (6) informed CBER that it has no direct evidence or information indicating that these vaccine batches were manufactured in a manner that would impact their safety, efficacy, or quality.



Accordingly, regardless of any assessment FDA makes regarding the Catalent facility's cGMP compliance at the time these batches were manufactured, Moderna has provided sufficient data and information for FDA to determine that these batches are suitable for use and that their known and potential benefits outweigh their known and potential risks for the use described in the Moderna COVID-19 EUA for bivalent boosters. Thus, the Agency has determined it is appropriate to amend the EUA for the Moderna COVID-19 Vaccine, Bivalent to include Moderna bivalent DP batches 017H22A, 021H22A, 013H22A, 019H22A, 020H22A, 023H22A, 049D22A, 061F22A and 024H22A . Additionally, in the event that FDA ultimately determines that the Catalent facility was not operating in compliance with cGMP requirements at the time these batches were manufactured, Condition I in the Moderna COVID-19 Vaccine Letter of Authorization will be waived as to these batches.